

Listing of Claims

1. (Presently Amended) A pharmaceutical composition comprising:

a medicament in a pharmaceutically acceptable effervescent formulation, said effervescent formulation comprising:

a gas-dispersing component including at least one first gas contained within an aqueous dissolvable solid matrix, and

a gas-generating effervescent component including at least two components reactive to generate a second gas upon aqueous contact.

2. (Original) The composition of claim 1 wherein the medicament is an agent chosen from an opioid analgesic agent, a non-opioid analgesic agent, an anti-inflammatory agent, an antitussive agent, an antipyretic agent, an antibiotic agent, an antimicrobial agent, a steroidal agent, an amphetamine stimulant agent, a non-amphetamine stimulant agent, a laxative agent, an anorexic agent, an antihistaminic agent, an antiasthmatic agent, an antidiuretic agent, an antifatulent agent, an antimigraine agent, an antispasmodic agent, an antidiabetic agent, a respiratory agent, a sympathomimetic agent, an H₂ blocking agent, an antihyperlipidemic agent, an antihypercholesterol agent, a cardiotonic agent, a vasodilating agent, a vasoconstricting agent, a sedative agent, a hypnotic agent, an anticonvulsant agent, a muscle relaxing agent, an antipsychotic agent, an antianxiolytic agent, an antihyperactive agent, an antihypertensive agent, an

antitumor agent, a soporific agent, a tranquilizer, a decongestant, a beta-blocker, a non-steroidal hormone, an herbal agent, an enzyme, a humoral agent, a madriatic agent, a psychic energizer, a vitamin, a mineral, and combinations thereof.

3. (Original) The composition of claim 1 wherein the matrix comprises a saccharide.

4. (Presently Amended) The composition of claim 1 wherein the matrix comprises an aqueous dissolvable material selected from the group consisting of sucrose, lactose, glucose, maltose, dextrose, fructose, fructosan, gentiobiose, cellobiose, panose, ~~maltotriose~~ maltotriose, ~~maltotetraose~~, maltotetraose, arabinose, mannose, galactose, amylose, allose, altose, talose, gulose, idose, ribose, erythrose, threose, lyxose, xylose, rhamnose, invert sugar, corn sugar, inositol, glycerol, glycogen, pectin, agar, sorbitol, mannitol, sucralose, polyols, tagarose, trehalose, xylitol, dextrins, dextrans, dextrans, polysorbates, maltodextrin, xylitol, amylase, amylopectin, ribose, β -maltose, fucose, sialic acid (neuraminic acid), N-acetylgalactosamine, N-acetylglucosamine, sedoheptulose, ribulose, xylulose, acesulfane potassium, aspartame, neotame, saccharin, stevioside, alitame, cyclamate, ~~dihydrochalcones~~ dihydrochalcones (DHCs), glycyrrhizin, thaumatin, gelatin, glycerin, triacetin, trehalose, alginates, gellan gum, guar gum, cellulose, microcrystalline cellulose, xanthan gum, cellulose acetate phthalate, low-substituted hydroxypropyl cellulose, hydropropylcellulose,

hydropropylmethylcellulose, ethylcellulose, methylcellulose, carrageenan, croscarmellose, povidone, crospovidone, starch, sodium starch glycolate, glucan, Adjumer[®] (polydi[carboxylatophenoxy]phosphazene), Pleuran (glycan), ~~Pluronic L-121~~ Pluronic[®] L121 (Poloxamer 401), glyceraldehyde, dihydroxyacetone, directly compressed dried honey and combinations thereof.

5. (Original) The composition of claim 1 wherein the matrix releases the at least one first gas upon contact with an aqueous vehicle containing at least about 0.1 ml of water.

6. (Original) The composition of claim 1 wherein the at least two components reactive to generate the second gas comprises at least one acidic component and at least one basic component.

7. (Original) The composition of claim 6 wherein the acidic component is chosen from citric acid, tartaric acid, malic acid, fumaric acid, adipic acid, lactic acid, succinic acid, disodium hydrogen phosphate, sodium dihydrogen phosphate, and combinations thereof.

8. (Original) The composition of claim 6 wherein the basic component is chosen from sodium carbonate, sodium bicarbonate, sodium sesquicarbonate, potassium carbonate,

potassium bicarbonate, potassium sesquicarbonate, magnesium carbonate, sodium glycine carbonate, L-lysine carbonate, arginine carbonate, amorphous calcium carbonate, ammonium carbonate, ammonium bicarbonate and combinations thereof.

9. (Original) The composition of claim 6 wherein the acidic component to basic component equivalence ratio is in a range from about 1:1 to about 1:10.

10. (Original) The composition of claim 6 wherein the acidic component to basic component equivalence ratio is in a range from about 1:2 to about 1:7.

11. (Original) The composition of claim 1 wherein the at least two components are capable of generating the second gas upon contact with an aqueous vehicle containing at least about 0.1 ml of water.

12. (Presently Amended) The composition of claim 1 wherein the at least one first gas is an inert gas chosen from carbon dioxide, nitrogen, air, helium, ethylene oxide, oxygen, and a combination thereof.

13. (Original) The composition of claim 1 wherein the second gas is carbon dioxide.

14. (Original) The composition of claim 1 wherein the first gas is the same as the second gas.

15. (Original) The composition of claim 1 wherein the first gas is different from the second gas.

16. (Original) The composition of claim 1 in an ingestible formulation chosen from an oral dispersible pill, a chewable pill, a buccal adhesive pill, a tablet, a capsule, a granular powder, a troche, and a dragée.

17. (Original) The composition of claim 1 in an ingestible formulation comprising a plurality of layers including an outermost layer and a core, the outermost layer containing at least one of the medicament, the solid gas-containing matrix, and the second gas-generating reactive components.

18. (Original) The composition of claim 1 in a solid formulation comprising a plurality of layers including an outermost layer and a core, the core containing at least one of the medicament, the solid gas-containing matrix, and the second gas-generating reactive components.

19. (Presently Amended) A pharmaceutical composition comprising a medicament in a pharmaceutically acceptable effervescent formulation, said effervescent formulation comprising:

a first component being a gas-dispersing component comprising a gasified at least one first gas contained within a water soluble solid matrix capable of abruptly releasing said at least one first gas upon contact with an aqueous vehicle, and

a second ~~effervescence~~ component being a gas-generating effervescent component comprising a gas-generating mixture of an acid and a base in a formulation substantially devoid of water, the mixture generating a second gas upon water contact.

20. (Original) The composition of claim 19 wherein the medicament is an agent chosen from an opioid analgesic agent, a non-opioid analgesic agent, an anti-inflammatory agent, an antitussive agent, an antipyretic agent, an antibiotic agent, an antimicrobial agent, a steroidal agent, an amphetamine stimulant agent, a non-amphetamine stimulant agent, a laxative agent, an anorexic agent, an antihistaminic agent, an antiasthmatic agent, an antidiuretic agent, an antiflatulant agent, an antimigraine agent, an antispasmodic agent, an antidiabetic agent, a respiratory agent, a sympathomimetic agent, an H₂ blocking agent, an antihyperlipidemic agent, an antihypercholesterol agent, a cardiotonic agent, a vasodilating agent, a vasoconstricting agent, a sedative agent, a hypnotic agent, an anticonvulsant agent, a muscle relaxing agent, an antipsychotic

agent, an antianxiolytic agent, an antihyperactive agent, an antihypertensive agent, an antitumor agent, a soporific agent, a tranquilizer, a decongestant, a beta-blocker, a non-steroidal hormone, an herbal agent, an enzyme, a humoral agent, a madriatic agent, a psychic energizer, a vitamin, a mineral, and combinations thereof.

21. (Original) The composition of claim 19 wherein the medicament is present in the formulation in an amount of about 1000 mg or less.

22. (Original) The composition of claim 19 wherein the medicament is present in the formulation in an amount ranging from about 25 mg to about 100 mg.

23. (Original) The composition of claim 19 wherein the medicament is present in the formulation in an amount of about 25 mg or less.

24. (Original) The composition of claim 19 wherein the first gas is the same as the second gas.

25. (Original) The composition of claim 19 wherein the first gas is different from the second gas.

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26. (Original) The composition of claim 19 in an ingestable formulation having a biconcave shape.

27. (Presently Amended) A method of administering a medicament to a patient, the method comprising:

providing to the patient a solid ingestable pharmaceutical composition comprising the ~~a~~ medicament, ~~an auto-dispersing first~~ a gas-dispersing component including a solid matrix having at least one first gas contained therein, and a ~~second~~ gas-generating effervescent component, the components reactive with an amount of an aqueous vehicle containing at least about 0.1 ml of water to generate the first and second gases, and

~~providing that the patient orally administers~~ administering the composition in an aqueous vehicle.

28. (Original) The method of claim 27 further comprising the patient selecting the aqueous vehicle for administering the composition.

29. (Original) The method of claim 27 further comprising instructing the patient to combine the composition with an amount of the aqueous vehicle containing up to about 5 ml of water.

30. (Original) The method of claim 27 further comprising instructing the patient to combine the composition with an amount of the aqueous vehicle containing at least about 5 ml of water.

31. (Original) The method of claim 27 further comprising instructing the patient to combine the composition with an amount of an aqueous vehicle containing water in an amount ranging about 5 ml to about 15 ml.

32. (Original) The method of claim 27 further comprising combining the composition with an aqueous vehicle containing at least about 0.1 ml of water.

33. (Original) The method of claim 27 wherein the aqueous vehicle is at least one of water, saliva, and a foodstuff.

34. (Original) The method of claim 27 further comprising administering the combination of the composition and the aqueous vehicle to the patient.

35. (Original) The method of claim 27 further comprising formulating the composition into one of an oral dispersible pill, a chewable pill, a buccal adhesive pill, a tablet, a

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capsule, a granular powder, a troche, and a dragée prior to providing the composition to the patient.

36. (Original) The method of claim 27 wherein the patient is a child.

37. (Presently Amended) A method of enhancing patient compliance with a pharmaceutical therapy, the method comprising:

providing to a patient an ingestible medicament formulated with a gas-dispersing component including at least one first gas contained within a dissolvable solid matrix, and a first effervescent component and a second effervescent component, the first effervescent component dispersing the medicament upon contact with an aqueous vehicle, and the second effervescent component enhancing penetration of the medicament; and

allowing the patient to select the aqueous vehicle for dispersion of the medicament in the aqueous vehicle.

38. (Original) The method of claim 37 wherein the patient is a child.

39. (Original) The method of claim 37 wherein the aqueous vehicle is at least one of water, saliva, and a foodstuff.

40. (Original) The method of claim 37 wherein the patient disperses the medicament in an amount of the aqueous vehicle containing at least about 0.1 ml of water.

41. (Presently Amended) A method of formulating an effervescent pharmaceutical composition, the method comprising:

formulating a biconcave multi-layered ingestible solid dosage formulation comprising (a) a medicament, (b) a ~~dispersing-gas~~ gas-dispersing component, and (c) a ~~substantially anhydrous-effervescent-penetration-enhancing-gas-precursor~~, the ~~dispersing-gas~~ gas-generating effervescent component, the gas-dispersing component comprising a solid aqueous-soluble matrix containing the at least one first gas, the ~~penetrating-gas-precursor~~ gas-generating effervescent component comprising an anhydrous admixture of an acid and a base capable of generating a gas upon aqueous contact, wherein at least one of (b) and (c) comprises an outer layer for initial aqueous contact.

42. (Original) The method of claim 41 wherein the pill is one of an oral dispersible pill, a chewable pill, and buccal adhesive pill.

43. (Presently Amended) The method of claim 41 wherein the aqueous-soluble matrix comprises an aqueous dissolvable material selected from the group consisting of sucrose, lactose, glucose, maltose, dextrose, fructose, fructosan, gentiobiose, cellobiose, panose, ~~malto-triose~~ maltotriose, ~~malto-tetrose~~, maltotetrose, arabinose, mannose, galactose, amylose, allose, altose, talose, gulose, idose, ribose, erythrose,

threose, lyxose, xylose, rhamnose, invert sugar, corn sugar, inositol, glycerol, glycogen, pectin, agar, sorbitol, mannitol, sucralose, polyols, tagarose, trehalose, xylitol, dextrans, dextrans, dextrates, polysorbates, maltodextrin, ~~xylitol~~, amylase, amylopectin, ribose, β -maltose, fucose, sialic acid (neuraminic acid), N-acetylgalactosamine, N-acetylglucosamine, sedoheptulose, ribulose, xylulose, acesulfane potassium, aspartame, neotame, saccharin, stevioside, alitame, cyclamate, ~~dihydrochalcones~~ dihydrochalcones (DHCs), glycyrrhizin, thaumatin, gelatin, glycerin, triacetin, trehalose, alginates, gellan gum, guar gum, cellulose, microcrystalline cellulose, xanthan gum, cellulose acetate phthalate, low-substituted hydroxypropyl cellulose, hydropropylcellulose, hydropropylmethylcellulose, ethylcellulose, methylcellulose, carrageenan, croscarmellose, povidone, crospovidone, starch, sodium starch glycolate, glucan, Adjumer[®] (polydi[carboxylatophenoxy][phosphazene), Pleuran (glycan), Pluronic-L-124 Pluronic[®] L121 (Poloxamer 401), glyceraldehyde, dihydroxyacetone, directly compressed dried honey and combinations thereof.

44. (Original) The method of claim 41 wherein the effervescent penetration enhancing gas precursor comprises at least one acidic component and at least one basic component having an acidic component to basic component weight ratio from about 1:1 to about 1:10.

45. (Original) The method of claim 44 wherein the acidic component is chosen from citric acid, tartaric acid, malic acid, fumaric acid, adipic acid, lactic acid, succinic acid, disodium hydrogen phosphate, sodium dihydrogen phosphate, and combinations thereof.

46. (Original) The method of claim 44 wherein the basic component is chosen from sodium carbonate, sodium bicarbonate, sodium sesquicarbonate, potassium carbonate, potassium bicarbonate, potassium sesquicarbonate, magnesium carbonate, sodium glycine carbonate, L-lysine carbonate, arginine carbonate, amorphous calcium carbonate, ammonium carbonate, ammonium bicarbonate and combinations thereof.

47. (Presently Amended) A method of dispersing a medicament in an aqueous vehicle, the method comprising:

providing to the patient a solid ingestible pharmaceutical composition comprising the ~~a~~ medicament, ~~an auto-dispersing first gas~~ a gas-dispersing component including a solid matrix having at least one first gas contained therein, and a ~~second~~ gas-generating effervescent component, the components to disperse the medicament in the an aqueous vehicle.

48. (Original) The method of claim 47 further comprising effervescing the aqueous vehicle to enhance penetration of the medicament in the vehicle.

49. (Original) The method of claim 48 further comprising dispersing the effervescence in the aqueous vehicle.

50. (Original) The method of claim 47 wherein the aqueous vehicle is saliva in the mouth of the patient.

51. (New) The composition of claim 1 wherein the at least one first gas is ethylene oxide.